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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,636	03/24/2004	Jun Feng	DPP-IV-5004-CI	7481
32793	7590	04/27/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			HABTE, KAHSAY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,636	FENG ET AL.	
	Examiner	Art Unit	
	Kahsay Habte	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-33, 36, 42, 43, 55-61, 87, 88, 95, 99, 100 and 103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/05, 8/2/05, 9/14/05 & 4/4/06</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11-14,34,35,37-40,41,44-54,62-86,89-94,96-98,101,102 and 104-114.

DETAILED ACTION

1. Claims 1-114 are pending in this application.

Election/Restriction

2. Applicant's election of a single species: 2-[2-(3-Amino-piperidin-1-yl)-6-fluoro-4-oxo-4H-quinazolin-3-ylmethyl]-benzonitrile (Example 6 disclosed at page 115 of the specification) filed 4/13/2006 is acknowledged. Claims 1-10, 15-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 are readable thereon. Claims 11-14, 34-35, 37-40, 41, 44-54, 62-86, 89-94, 96-98, 101-102 and 104-114 are drawn to non-quinazoline compounds, stand withdrawn from further consideration as not being readable on the elected species. Since the elected species is free of prior art, the search was extended.
3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. For example, in claim 32 the phrase "or heterocycloalkyl ring" is a non-elected subject matter.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 2/23/2005, 8/2/2005, 9/14/2005 and 4/4/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7, 16-19, 22-23, 25-27, 30-33, 41-43, 87-88, 99 and 103 are rejected under 35 U.S.C. 102(a) as being anticipated by Kesarwani et al. *Tetrahedron Letters* 43 (2002) 5579-5581. Cited reference discloses a compound of interest: 3-(phenylmethyl)-2-[4-(phenylmethyl)-1-piperidinyl]-4(3H)quinazolinone at page 5580 that is the same as applicants when applicant's Formulae X, XI, XVIIa, XVIIb and XVIIc have the following substituents:

Q = CO; R₁ = benzyl (i.e. Z = CH₂ and R_m = phenyl); and R₂ = piperidinyl substituted with benzyl.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 15-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term “substituted” is indefinite. In the absence of the specific moieties intended to effectuate modification by the “substitution” or attachment to the chemical core claimed, the term “substituted” renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. In claim 1 or elsewhere in the claims, the phrase “U is a moiety” is indefinite. What is covered by U and what is not?

c. In claim 1 or elsewhere in the claims, the term “comprising” is an open-ended language. It is recommended that applicants delete said term from the claims.

d. In claim 1 or elsewhere in the claim, the phrase “V comprises a basic nitrogen atom that is capable of interacting with a carboxylic acid side chain of an active site residue of a protein” is not clear. Is the ring nitrogen capable of interacting with carboxylic acid or the substituent on the ring is capable of interacting with carboxylic acid? The term “comprises” is also an open-ended language.

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e. In claim 1, the phrase "R₃ and R₄ are taken together to form...5 or 6-membered ring" is indefinite. What is the nature of the ring? What is covered and what is not? It is recommended that applicants amend the claim as "R₃ and R₄ are taken together to form...a benzo ring".

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-10, 15-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims and claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte
Primary Examiner
Art Unit 1624

April 26, 2006